Oral Appliance Treatment for Obstructive Sleep Apnea: Impact on Oral Health Quality of Life and its Relationship to Sleep-Related Quality of Life

A THESIS SUBMITTED TO THE FACULTY
OF THE DIVISION OF DENTAL HYGIENE SCHOOL OF DENTISTRY
UNIVERSITY OF MINNESOTA

BY

Julie Mae Klegin

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF
MASTER OF SCIENCE IN DENTAL HYGIENE

Sheila M. Riggs DDS, MS, DMSc, Advisor

July 2019

ACKNOWLEDGEMENTS

Thank you to my parents, Larry and Deb, for always being supportive and encouraging throughout my educational career.

Thank you to my advisor, Dr. Sheila M. Riggs, for all your help and support during my thesis.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

SECTION 1

INTRODUCTION

Obstructive sleep apnea (OSA) affects an estimated 20 million persons in the United States with a large number of these individuals experiencing a severe form of OSA.[1] Persons with OSA experience repetitive pauses or shallow breathing during sleep that can last up to 10 seconds.[2] These pauses and shallow breathing are due to collapsing or blocking of the upper airway.[2] Persons with OSA experience frequent sleep disturbances throughout the night which can affect daytime sleepiness, concentration, mood, headaches, personal life and snoring.[3] Untreated OSA can also affect systemic health conditions by increasing the risks for cardiovascular disease, diabetes, neurological disorders and social and emotional problems which can all impact a person's quality of life.[2,3] There are treatment options for OSA such as oral appliances. However, oral health risks are associated with using oral appliances that should be considered before treatment because it can significantly impact a person's quality of life.

Purpose of the Study

The purpose of this study is to understand how oral appliance treatment for persons with obstructive sleep apnea impacts their oral health quality of life and its relationship between sleep-related quality of life and oral health quality of life.

Statement of the Problem

OSA is a sleep disorder that causes shallow breathing or pauses during sleep due to collapsing or blocking of the upper airway.[2] To improve this condition, oral appliances should be worn during sleep to help keep airways open so normal breathing can occur.[3] Oral appliance treatment can provide positive changes in a person's quality of life

relating to daytime tiredness, concentration, mood, systemic health and personal and professional life.[2] However, research has shown that use of oral appliances can negatively affect the mouth.[4] Oral appliances create a protrusive positioning of the mandible when worn, causing pain and discomfort in the temporomandibular joint.[4] Further research relating to other oral health adverse effects from use of oral appliances are limited. In response to this problem, this study proposes to identify how oral appliances for OSA impacts a patient's oral health quality of life. Through measured outcomes preformed in this study, data collection will show how oral health quality of life is impacted by oral appliance use and determine the relationship between sleep-related quality of life and oral health quality of life.

Significance of the Study

The significance of this study was to provide dental professionals knowledge relating to oral health quality of life and sleep-related quality of life for persons with OSA. This information will allow dental professionals to educate and ease patients concerns relating to their quality of life after being diagnosed with OSA. Persons with OSA will benefit from this study by understanding how oral appliances impact their quality of life through oral function, orofacial appearance, orofacial pain and psychosocial impact.[5] When patients are diagnosed with OSA, many struggle with the unknown relating to delayed diagnosis, lack of knowledge, support, follow-up and difficultly adhering to oral appliance treatment.[1] Patients can have difficulty with adjusting to initial oral appliance treatment but also the adverse effects and challenges that can result by not being fully informed.[1] Patients can better prepare for treatment

outcomes by understanding oral health adverse effects associated with use of oral appliance treatment and how it impacts their oral health quality of life and sleep-related quality of life through this study.

Research Questions

1. For persons with obstructive sleep apnea, what is the impact of oral appliance treatment on oral health quality of life?
2. For persons undergoing oral appliance treatment for obstructive sleep apnea, what is the relationship between sleep-related quality of life and oral health quality of life?

Hypotheses

1. There is no relationship between oral appliance treatment and oral health quality of life for persons with obstructive sleep apnea.
2. There is no correlation between sleep-related quality of life and oral health quality of life for persons undergoing oral appliance treatment for obstructive sleep apnea.

SECTION 2

REVIEW OF THE RELATED LITERATURE

A comprehensive review of the literature was conducted using Medline and PubMed electronic bibliographic databases. Articles pertaining to obstructive sleep apnea treatment, sleep apnea quality of life, oral health quality of life and sleep-related quality of life were included. Type of articles include peer reviewed journals and editorials. These articles were published between 2006 and 2019. The final date of the search strategy was September 15, 2018. The theoretical framework used was self-management theory. Self-management theory promotes improved outcomes and will provide future research a foundation to evaluate and assess the effect of providing therapy that meets the goals and needs of the individuals to promote participation and self-management with OSA.[1]

OSA can become a serious health condition. Due to blocked or restricted airway during sleep, persons with OSA can experience sleep disturbances that can increase daytime sleepiness, lack of concentration, fatigue, headaches and personal and professional life.[3] If OSA is left untreated, there are increased risks for systemic health complications including cardiovascular disease, diabetes, neurological disorders that can significantly impact a person's quality of life.[2,3]

To improve OSA condition, normal breathing needs to occur by widening the respiratory space.[6] Treatment options for OSA include continuous positive airway pressure (CPAP), surgical removal of the soft tissue in the throat and oral appliances known as mandibular advancement device (MAD).[6] The use of a CPAP device delivers air pressure through a face mask and hose connected to a flow generator.[1] The continuous

air pressure being delivered helps keep airways open by preventing soft tissues from collapsing during sleep.[1] CPAP has been shown to be most effective for OSA treatment, however, patient acceptance, adherence and tolerance to the oral appliance treatment is low.[1,3,4] Less than half of people prescribed for CPAP treatment adhere long-term.[1] For CPAP device to be effective, a person must wear the device for at least 4 to 5 hours a night.[1]

MAD is designed to prevent collapsing of the upper airway by altering the positioning of the jaw and tongue.[4] The device lowers the jaw into a protruded position to open the airways.[4] There are many designs available for MAD targeted towards degree of advancement, vertical opening, fabrication material and occlusal coverage.[4] The oral appliance treatment design will be determined by a dentist to meet the needs of the patient.[6] The use of MAD has shown to be successful in reducing respiratory disturbances.[6] OSA conditions of mild and moderate have improved by 57-81% and severe cases by 14-61% with use of MAD.[5] Patients have many options for treating OSA and should consult with their physician to understand what is best for them.

When diagnosed with OSA, many patients struggle with the unknown relating to delayed diagnosis, lack of knowledge, support, follow-up and difficultly adhering to oral appliance treatment.[1] Patients can have difficulty with adjusting to initial oral appliance treatment but also the adverse effects and challenges that can result by not being fully informed.[1] Oral health adverse effects that patients can experience from OSA treatment include hyper salivation, dry mouth, tooth pain, gum irritation, headaches, malocclusion, tinnitus and temporomandibular joint discomfort.[4] There has also been shown to be an

association between OSA and periodontal disease that can affect many individuals living with OSA.[7] Patient experiences before and after use with oral appliance treatment was also reported to further understand patient experiences with oral appliances and OSA.

Relationship between OSA and other Health Conditions

There is an association between the cardiovascular system and OSA condition.[8] During respiratory distress, the blocked airway creates a negative thoracic pressure that causes pressure in the left and right ventriculars.[8] The increased pressure can affect the cardiac muscles in many ways.[8] The walls of the left and right ventricular can start to thicken over time, due to the increased pressure.[8] Apnea-induced oxygen deficiency can lead to pulmonary vasoconstriction.[8] Oxygen deficiency can also result in pressure that initiates inflammatory pathways that weaken vascular function.[8] The sudden sleep disturbances with OSA can increase sympathetic nervous system responses and alter parasympathetic nervous system responses.[8] Cardiovascular changes that occur due to sleep disturbances from OSA can result in increased blood pressure and heart rate during sleep and daytime activity which can lead to myocardial infarction, congestive heart failure and even possible death.[8]

A study by Cistulli et al concluded that use of OSA treatment such as CPAP and MAD have significantly improved cardiovascular conditions.[4] Several studies demonstrated improvements in patient's blood pressure and overall vascular function with OSA oral appliance treatment.[8] The use of CPAP and MAD improve oxygen levels while individuals sleep; which in long-term can result in improved quality of life for persons with OSA.[2] There is not a significant difference between using CPAP and MAD

when considering treatment outcomes for cardiovascular health.[4,8]

Diabetes has a positive correlation with OSA condition due to shared risk factors.[9] The two major characteristics of OSA include irregular oxygen deficiency and sleep disturbances which can lead to changes in glucose metabolism.[9] Studies have shown that there is a systemic inflammation and blood coagulation state that occurs in patients with OSA.[10] When evaluating glycemic control with CPAP treatment for patients with OSA, research found that 59% of diabetic patients saw improved HbA1c levels which can greatly impact management of diabetes.[9] Research evaluating the impact of MAD treatment and its relationship with inflammatory and bleeding measures for patients with OSA found no significant changes with inflammatory and bleeding measures.[10] However, apnea-induced oxygen deficiency levels had an improvement seen after three months of MAD treatment and even further improvement at six months.[10]

There is an association between neurological disorders and OSA condition due to a reaction of hemoglobin with oxygen relating to sleep disturbances.[2] Neurological adverse effects that can result include depression, irritability, impaired cognition, difficulty concentrating, short-term memory loss and mood disorders.[2] These neurological adverse effects can impact a person's everyday life.[2] Personal and professional relationships can be affected and even possible driving and workplace accidents.[2] Studies have shown that CPAP treatment can improve neurological symptoms associated with OSA condition.[2] A persons daily performance relating to both personal and professional life saw improvement within the studies which can help improve patients overall quality of life.[2]

Influence of OSA on Oral Health

OSA and oral appliance treatment not only affects systemic health but also a person's oral health. Evidence has shown that persons with OSA are at an elevated risk for developing chronic pain disorders such as temporomandibular disorder (TMD).[11] TMD is characterized as a musculoskeletal disorder consisting of recurring pain in the temporomandibular joint and regions in the masticatory muscle.[11] Symptoms that can occur with TMD include inability to open and close without pain, stiffness, ear pain, and clicking and locking of the temporomandibular joint.[12] When measuring the association between MAD treatment and TMD, research has shown that MAD treatment puts excessive pressure on the mandible that pushes it into a protrusive position, creating discomfort and pain in the temporomandibular joint.[12] Patients experienced more TMD discomfort and pain associated with MAD treatment compared to use of CPAP treatment.[12] For patients who already experienced TMD discomfort, these individuals stopped using their MAD treatment more often than compared to patients without TMD issues.[12] Continuing with MAD treatment long-term does not automatically increase a person's risk of TMD symptoms to progress, however, further evaluation is needed to fully understand the effect of oral appliance treatment relating to TMD issues.[12]

There is an unclear association between OSA and periodontitis but there are common risk factors to consider. Severe periodontitis can contribute to a greater inflammatory load which can increase the host response to bacteria in persons with OSA.[7] Common risk factors that OSA and periodontitis share include similar inflammatory pathways, disease formation, and other contributing risk factors.[7]

Xerostomia is commonly experienced by persons with OSA due to repetitive snoring and mouth breathing during sleep.[7] Xerostomia is also a common risks factor for periodontitis because it intensifies the growth and formation of bacteria and plaque.[7] OSA treatment with CPAP can help reduce periodontitis severity by improving levels of oxygen.[7] However, more studies are needed to fully understand the relationship of periodontitis and OSA and the role of oral appliance treatment.

Other oral health conditions that can develop from OSA treatment include overbite and overjet changes.[4] Due to the thickness of oral appliances, it can cause vertical jaw displacement resulting in overbite and overjet changes.[4] Patients may also experience xerostomia or hyper-salivation as common adverse effects of oral appliance treatment. Oral appliances can also increase the risk for tinnitus.[13] Tinnitus is a ringing sound within the ear that can awaken a person during sleep.[13] Research has shown that patients with long-term use of oral appliance treatment for OSA do experience tinnitus, however, it is an uncommon oral health adverse effect.[13] Although there are many oral health changes that occur with OSA treatment, patients still consider the end results with oral appliance treatment to exceed the negative effects that occur to their oral health.[4] It is important that patients are aware of all the oral health adverse effects associated with oral appliance treatment to understand all potential treatment outcomes.

Patient Experiences with Oral Appliances

A study by Nordin et al was conducted to evaluate patients self-reported experiences before and after use of oral appliance treatment for OSA.[6] The study assessed patients based on criteria including feeling rested after a night's sleep, daytime tiredness,

sleep disturbances occurring at least two times during sleep, snoring, increased social and emotional issues and difficulty concentrating.[6] Participants reported high scores of each of the following criteria before use of oral appliances.[6] After use of oral appliances, participants within the study reported significant improvements in all of the areas evaluated.[6] Participants also experienced significant improvements in their physical strength, well-being and quality of life.[6] Participants reported a 39% improvement in their quality of life after using oral appliances for OSA and 85% reported they would recommend oral appliances for treatment of OSA.[6]

When diagnosed with OSA, many patients struggle with the unknown relating to delayed diagnosis, lack of knowledge, support, follow-up and difficultly adhering to oral appliance treatment.[1] Adequate information and resources are limited relating to oral appliance treatment and its effects on oral health quality of life and sleep-related quality of life for persons with OSA. By understanding oral health adverse effects associated with use of oral appliance treatment, patients can better prepare for treatment outcomes and how it will impact their quality of life. Therefore, the purpose of this study is to further understand how oral appliance treatment for obstructive sleep apnea impacts oral health quality of life and its relationship to sleep-related quality of life.

SECTION 3

SUMMARY

Study Objectives. To understand how oral appliance treatment for persons with obstructive sleep apnea (OSA) impacts their oral health quality of life and the relationship between sleep-related quality of life and oral health quality of life.

Methods. An observational study was performed. Study participants were persons diagnosed with OSA who were undergoing oral appliance treatment at the University of Minnesota Physicians Dental Clinic. Participants were treated with a mandibular advancement device. Oral Health Impact Profile 5-Item (OHIP5) survey and Sleep-Related Quality of Life (SRQL) survey were used.

Results. 61 participants met the inclusion criteria of assessment, splint insert and at least one follow-up survey. A significant difference between splint insert and follow-up appointments for SRQL survey questions had a p-value of <.0001. OHIP5 survey questions had a p-value of 0.1281, indicating no statistical significance between splint insert and follow-up appointments. Pearson's correlation coefficient showed a weak correlation between oral health problems and sleep disturbance, sleep related impairment and sleepiness issues with an average mean score below 0.4.

Conclusion. As expected, patients experienced self-reported improvement with sleep disturbance, sleep related impairment and sleepiness issues while using an oral appliance. SRQL was improved for patients when using a mandibular advancement device for OSA. Dental professionals can educate and inform OSA patients that oral appliances such as mandibular advancement devices used in this study, while improving sleep-related quality of life, do not impact oral health quality of life. There was also a weak correlation

found between oral health problems and sleep disturbance, sleep related impairment and sleepiness issues.

Keywords. obstructive sleep apnea, oral appliance, mandibular advancement device, oral health impact profile, oral health quality of life, sleep-related quality of life

MANUSCRIPT

This manuscript will be submitted to the *Journal of Dental Sleep Medicine (JDSM).*

Introduction and Literature Review

Obstructive sleep apnea (OSA) is a sleep disorder that causes shallow breathing or pauses during sleep due to collapsing or blocking of the upper airway.[2] OSA affects an estimated 20 million persons in the United States with a large number of these individuals experiencing a severe form of OSA.[1] Persons with OSA experience frequent sleep disturbances throughout the night which can affect daytime sleepiness, concentration, mood, headaches, personal life and snoring.[3] Untreated OSA can affect systemic health by increasing the risks for cardiovascular disease, diabetes, neurological disorders and social and emotional problems which can all impact a person's quality of life.[2,3] Patients can also experience oral health effects from OSA treatment such as hyper-salivation, dry mouth, tooth pain, gum irritation, malocclusion, tinnitus and temporomandibular joint discomfort.[4] It is important for patients to understand the oral health risks associated with using oral appliances before deciding treatment options because it can significantly impact a person's quality of life.

Treatment options for OSA include continuous positive airway pressure (CPAP), surgical removal of the soft tissue in the throat and oral appliances known as mandibular

advancement device (MAD).[6] The use of a CPAP device delivers air pressure through a face mask and hose connected to a flow generator.[1] The continuous air pressure being delivered helps keep airways open by preventing soft tissues from collapsing during sleep.[1] CPAP has been shown to be most effective for OSA treatment, however, patient acceptance, adherence and tolerance to the oral appliance treatment is low.[1,3,4] MAD was designed to prevent collapsing of the upper airway by altering the positioning of the jaw and tongue.[4] The device lowers the jaw into a protruded position to open the airways.[4] The use of MAD has shown to be successful in reducing respiratory disturbances.[6] Patients have many options for treating OSA conditions. Patients should consult with their physician to understand what is best for them.

Untreated OSA can affect systemic health significantly. Studies have shown that OSA treatment such as CPAP and MAD have significantly improved cardiovascular conditions.[4] Patients had improvement in blood pressure and overall vascular function.[8] Apnea-induced oxygen deficiency levels was also improved after three months of using MAD treatment and even further improvement at six months.[10] Oxygen deficiency can lead to changes in glucose metabolism which greatly impacts persons with diabetes.[9] There is also an association between neurological disorders and OSA condition.[2] Studies have shown that CPAP treatment can improve neurological symptoms through improved daily performance in personal and professional life.[2]

OSA and oral appliance treatment not only affects systemic health but also a person's oral health. Studies has shown that persons with OSA are at a high risk for developing chronic pain disorders such as temporomandibular disorder (TMD).[11] Oral

appliances such as MAD puts excessive pressure on the mandible that pushes it into a protrusive position, creating discomfort and pain in the temporomandibular joint.[12] Studies have found that patients do experience temporomandibular joint pain while wearing MAD appliances.[12] There has also been shown an association between severe periodontitis and OSA.[7] Periodontitis can contribute to a greater inflammatory load which can increase the host response to bacteria in persons with OSA.[7]

Other oral health conditions that can develop from OSA treatment include overbite and overjet changes.[4] Due to the thickness of oral appliances, it can cause vertical jaw displacement resulting in overbite and overjet changes.[4] Xerostomia or hyper-salivation are common adverse effects of oral appliance treatment too. Oral appliances can also increase the risk for tinnitus, a ringing sound within the ear that can awaken a person during sleep.[13] Although there are many oral health changes that occur with OSA treatment, patients still consider the end results with oral appliance treatment to exceed the negative effects that occur to their oral health.[4]

A study by Nordin et al was conducted to evaluate patients self-reported experiences before and after use of oral appliance treatment for OSA.[6] The study assessed patients based on criteria including feeling rested after a night's sleep, daytime tiredness, sleep disturbances occurring at least two times during sleep, snoring, increased social and emotional issues and difficulty concentrating.[6] Participants reported high scores of each of the following criteria before use of oral appliances.[6] After use of oral appliances, participants within the study reported significant improvements in all of the areas evaluated.[6] Participants also experienced significant improvements in their physical

strength, well-being and quality of life.[6] Participants reported a 39% improvement in their quality of life after using oral appliances for OSA and 85% reported they would recommend oral appliances for treatment of OSA.[6]

Understanding the best treatment options can be difficult for patients when being diagnosed with OSA. Adequate research is limited relating to oral appliance treatment and its effects on oral health quality of life and sleep-related quality of life for persons with OSA. By understanding oral health adverse effects associated with use of oral appliance treatment, patients can better prepare for treatment outcomes and how it will impact their quality of life.

Methods and Materials

This observational study investigated the impact of oral appliance treatment on oral health quality of life and investigated the relationship between sleep-related quality of life and oral health quality of life for persons with OSA. Participants were treated with a mandibular advancement device. The independent variable was oral appliance treatment and the dependent variables were oral health quality of life and sleep-related quality of life. The study setting was the University of Minnesota Physicians Dental Clinic. The timeframe for this study was February 2015 to August 2018.

Subjects. The study participants were patients with diagnosed OSA who were undergoing oral appliance treatment at the University of Minnesota Physicians Dental Clinic. All participant surveys querying oral health and sleep-related quality of life became a part of the patient's health record. Inclusion criteria for selection of participants included diagnosis of OSA, need for oral appliance treatment, all 27 survey questions answered,

all three surveys of assessment, splint insert and at least one follow-up survey completed. Exclusion criteria for selection of participants included no diagnosis of OSA, no need for oral appliance treatment, incomplete survey answers and all three surveys of assessment, splint insert and at least one follow-up survey not completed. Table I provides the exclusion criteria with the number of participants in each category.

Data Collection. Secondary data was obtained via the University of Minnesota Physicians Dental Clinic's database. Permission to use existing data from the University of Minnesota sleep clinic was obtained from the University of Minnesota Institutional Review Board. At the sleep clinic, patients were required to fill out the Oral Health Impact Profile 5-Item (OHIP5) survey and the Sleep-Related Quality of Life (SRQL) survey prior to each appointment. The same survey instrument was administered multiple times during treatment.

The first appointment was assessment, second appointment was splint insert that occurred four weeks later and a third follow-up appointment occurred two weeks later. Patients continued to have follow-up appointments every two weeks until the oral appliance fit correctly. At each appointment, patients completed the survey instrument under similar conditions while answering the OHIP5 and SRQL survey questions. Once the oral appliance was titrated, the final position of the MAD was determined and patients came back every six months for follow-up appointments. Participants in the study had a variety of follow-up appointments depending on the need for further treatment. Some participants had one follow-up appointment and some participants had six follow-up appointments. All follow-up surveys were used to collect an average mean

score. The entire course of treatment for each patient was not included within the data collection. Only completed surveys between the study timeframe of February 2015 to August 2018 were included. Data collection consisted of manually entering 764 paper survey forms into Microsoft Excel database with a total of 255 participants.

Data Collection Instruments. Two instruments were used for data collection. Oral Health Impact Profile 5-Item survey and Sleep-Related Quality of Life survey. The instruments measured individual's oral health and sleep-related quality of life relating to OSA while receiving oral appliance treatment. The OHIP5 survey consisted of five questions on oral health problems that occurred within the last seven days for patients.[14] The SRQL survey consisted of six questions on sleep disturbance, eight questions on sleep-related impairment and eight questions on sleepiness. The survey questions are provided in appendix B. The two surveys were combined into one large survey with a total of 27 questions. No examiner calibration was needed due to the data collection was completed by each participant individually.

OHIP is one of the most widely oral health related quality of life instruments.[15] OHIP5 was used in this study which is the shortest OHIP survey.[15] It captures 90% of the 49-item instrument's score information making it an efficient tool for oral health quality of life measurment.[15,16] OHIP5 has been validated to the adult general population as a reliable and valid instrument.[15,16] The SRQL survey has been validated as a simple and reliable method to measure individual's daytime sleepiness, sleep disturbance and sleep related impairment.[17,18] A standardized questionnaire such as the SRQL survey provides clinically useful measurements of a person's general level of sleep health.[17,18]

The survey instruments answered the research questions through addressing oral health and sleep-related quality of life relating to oral appliance treatment for patients with OSA. The surveys addressed questions regarding patient's self-reported experiences before using oral appliance treatment, during treatment and follow-up treatment. The format for the survey questions was ordinal rating scale. The Apnea-Hypopnea Index (AHI) was also collected to enhance this study by understanding participant's severity of OSA.[19,20] AHI classifies patients as a mild, moderate or severe diagnosis.[19,20] AHI was not within the research questions and not adjusted for within this study.

Internal validity for this study included repeated testing due to patients having experience answering the same questions on the survey from previous appointments. Also, self-reporting internal validity due to patients self-reporting on their experiences which makes it difficult to know if responses are honest and valid. External validity for this study included that results may not be generalizable to other institutions due to this study being completed only at the University of Minnesota Physicians Dental Clinic.

Statistical Analysis. The demographics information and baseline characteristics are presented as mean +/- and standard deviation (SD). OHIP5 survey and SRQL survey were summarized by including participants who had complete surveys of assessment, splint insert and at least one follow-up survey. The alpha level for this study was 0.05 used for statistical significance. To evaluate the effect of the oral appliance treatment, paired t-test and linear regression mixed model were applied to compare oral health quality of life scores and sleep-related quality of life scores at different time points. The linear regression mixed model used survey score as outcome and survey type, age and

gender as fixed effects with a random intercept by subject. The analysis for this study coded the categorical answers as numbers and added them up for a composite score. The higher the number, the worse the patient was doing in that area. Pearson correlation coefficient was calculated to determine the relationship between oral health quality of life scores and sleep-related quality of life scores. The statistical software for this study was R (v 3.5.1). Approval of methods and treatment of human subjects in this study was confirmed by the Institutional Review Board of the University of Minnesota.

Operational Definitions.

- OSA was defined as a sleep disorder that causes shallow breathing or pauses during sleep due to collapsing or blocking of the upper airway.
- Oral appliance treatment was defined as an oral device used to deliver continuous air pressure to keep airways open during sleep (continuous positive airway pressure appliance) and to prevent collapsing of the upper airway by altering the positioning of the jaw and tongue (mandibular advancement device).
- Oral health quality of life was defined as oral health problems relating to the mouth, teeth and jaw experienced by patients who used oral appliance treatment for OSA.
- Sleep-related quality of life was defined as sleepiness, sleep-related impairment and sleep disturbances experienced by patients who used oral appliance treatment at night for OSA.

Results

After inclusion criteria were applied to the 255 study participants, 61 participants completed the assessment, splint insert, and follow-up surveys. The 194 participants who did not meet the inclusion criteria were eliminated from this study and the collected information was not included. Figure I shows participants answers for each of the 27 survey questions. The mean (SD) scores for assessment, splint insert, and follow up surveys are provided in table II. Table II shows scores for all sections of the survey; sleep disturbance, sleep related impairment, sleepiness and oral health problems. The demographic factors (age, gender) were not significant within this study. Of the 61 participants, the average age was 49 years; 24 were female and 37 were male.

The oral health survey section had an assessment average mean of 1.69, splint insert average mean of 1.34 and a follow-up average mean of 1.63. The results showed participant's oral health was not affected while using the oral appliance. The linear regression mixed model also showed no statistical significance from the splint insert appointment to the follow up appointments with a p-value of 0.1281. The p-value for the assessment appointment to the splint insert appointment was 0.2239, demonstrating no statistical difference in oral health between assessment and splint insert appointments. Participants in the study experienced no changes in their oral health quality of life while using an oral appliance.

Within the sleep disturbance survey section, the average mean for assessment surveys was 9.45, average mean for splint insert surveys was 9.7 and the average mean for follow-up surveys was 7.42. The results showed participant's experienced less sleep

disturbance issues from their splint insert appointment to their last follow-up appointments from using an oral appliance. The linear regression mixed model also showed a significant difference from the splint insert appointment to the follow up appointments. The p-value was < .0001, indicating statistical significance. The p-value for the assessment appointment to the splint insert appointment was 0.7561, demonstrating no difference in participant's sleep disturbance between assessment and splint insert appointments.

The sleep related impairment survey section had an assessment average mean of 10.58, splint insert average mean of 10.93 and follow-up average mean of 8.06. The results showed participant's sleep related impairment problems had improved from their splint insert appointment to their last follow-up appointments while using the oral appliance. The linear regression mixed model also showed a significant difference from the splint insert appointment to the follow up appointments. The p-value was < .0001, indicating statistical significance. The p-value for the assessment appointment to the splint insert appointment was 0.7876, demonstrating no difference in participant's sleep related impairment between assessment and splint insert appointments.

The sleepiness survey section had an assessment average mean of 7.94, splint insert average mean of 7.18 and a follow-up average mean of 5.73. The results showed participant's sleepiness had improved while using the oral appliance. From participant's splint insert appointment to their last follow-up appointments, participant's experienced less sleepiness issues while using an oral appliance. The linear regression mixed model also showed a significant difference from the splint insert appointment to the follow up

appointments with a p-value of 0.0051. The p-value for the assessment appointment to the splint insert appointment was 0.0287, indicating a significant difference between assessment and splint insert appointments relating to patient's sleepiness.

To analyze the relationship between sleep-related quality of life and oral health quality of life for patients undergoing oral appliance treatment, Pearson's correlation coefficient was performed. Table III shows the correlation between oral health problems and sleep issues. Results found that sleep disturbance survey had a mean of 0.386, sleep related impairment survey had a mean of 0.383 and sleepiness survey had a mean of 0.112. An average mean score above 0.7 indicated a high correlation, an average mean score between 0.7-0.4 indicated a moderate correlation and an average mean score below 0.4 was a weak correlation. The results showed that sleep disturbance, sleep related impairment, and sleepiness surveys all had a weak correlation with an average mean below 0.4. Results concluded that there was a weak correlation between sleep-related quality of life and oral health quality of life for patients undergoing oral appliance treatment for OSA.

The average AHI mean score for the 61 participants was 19. Patients with AHI scores between 5<15 are classified as mild sleep apnea, AHI scores between 15<30 are classified as moderate sleep apnea and AHI scores 30 and greater are classified as severe sleep apnea.[19,20] Participants in the study had a moderate level of sleep apnea with a mean score of 19. Figure II shows a bar graph of the AHI values for all 61 participants.

Discussion

In this observational study, the performance of the OHIP5 survey and SRQL survey were evaluated. These two instruments measured individual's oral health quality of life and sleep-related quality of life while undergoing oral appliance treatment for OSA. The SRQL survey provides clinically useful measurements of an individual's daytime sleepiness, sleep disturbance and sleep related impairment health.[17,18] The SRQL survey is a simple and reliable twenty-two item standardized questionnaire. The participants within this study all experienced improvement in their SRQL while using oral appliances for OSA.

The results from the SRQL survey were expected, oral appliances are designed to improve patients SRQL. MAD treatment used in this study was designed to prevent collapsing and blocking of the upper airway during sleep to help decrease sleep disturbances throughout the night.[4] Other studies have also seen improvement in patient's respiratory disturbances and sleepiness issues with oral appliances.[4, 6] When compared to previous studies, results were common among patients experiencing a decrease in daytime sleepiness, decrease in sleep related impairment involving concentration and feeling alert and improvement with respiratory disturbances during sleep when using oral appliances for OSA.[4, 6]

The OHIP5 survey instrument determined an individual's oral health quality of life when using oral appliances for OSA. OHIP is one of the most widely oral health related quality of life instruments.[15] It captures 90% of the 49-item instrument's score information making it a valid and efficient tool for oral health quality of life

measurment.[15,16] Ultrashort instruments such as the 5-item OHIP allows for minimal collection of data that still provides quality measurement of oral disorders and dental intervention for participants.[15] The participants within this study self-reported no changes in their oral health conditions while using an oral appliance. The results from the OHIP5 survey were not surprising because oral appliances are not designed to impact oral health conditions. The main goal with oral appliance treatment for OSA is to widen the airway and prevent collapsing through adjustment of the jaw and tongue position.[4] Other studies however, have shown negative effects of oral appliances to patient's oral health due to long term use that can affect oral health conditions such as temporomandibular joint, tooth pain, malocclusion and dry mouth.[4]

This study only evaluated short term impact of MAD on oral health and sleep-related quality of life. When comparing MAD to CPAP treatment for OSA, studies have shown that CPAP is an effective treatment for OSA, however, patient acceptance, adherence and tolerance to this oral appliance treatment is low.[1,3,4] Less than half of people prescribed for CPAP treatment adhere long-term.[1] Previous studies have not shown that CPAP affects oral health conditions negatively as MAD treatment does. However, MAD treatment has proven to be effective too. OSA conditions of mild and moderate have improved by 57-81% and severe cases by 14-61% with use of MAD.[6] There are many aspects of diagnosis and treatment for OSA patients and the impact it has on sleep-related quality of life and oral health quality of life.

It is possible participants in this study did not experience any self-reported oral health problems because this could have been their first time using an oral appliance and

it didn't impact their oral health as much as it would a patient who has undergone oral appliance treatment before. Another reason could be that the participants did not wear the oral appliance every night as instructed to experience any oral health symptoms. It is also important to take into consideration that each patient experiences treatment outcomes differently. Some patients do experience oral health problems from oral appliances and some, like in this study, will not experience any oral health problems.

The results from the Pearson's correlation coefficient found that there was a weak correlation between SRQL and oral health quality of life for patients undergoing oral appliance treatment. These results were not surprising because there is a limited relationship between SRQL and oral health quality of life that would impact each other. When comparing to other studies, there is lack of research on this topic to fully understand if there is a relationship between SRQL and oral health quality of life.

The results from AHI had a mean score of 19, resulting in a diagnosis of moderate sleep apnea for the typical participant in this study. These results indicated that participants in the study experienced on average 19 apnea or hypopnea (pauses in breathing) per hour of sleep. Participants severity of OSA in this study was fairly high, resulting in need of oral appliance treatment to control their OSA by lowering their AHI.

A major limitation in this study was the sample size. The inclusion criteria for selection of participants included diagnosis of OSA, need for oral appliance treatment, completed surveys of assessment, splint insert and at least one follow-up with all 27 questions answered. Only 61 of the 255 participants met these criteria. To better understand the impact of oral appliance treatment on oral health quality of life and the

relationship between SRQL and oral health quality of life, more studies with a larger sample size are needed.

Another limitation in this study was the variety of follow-ups used. Of the 61 participants, 21 had one follow-up survey, 16 had two follow-up surveys, 12 had three follow-up surveys, eight had four follow-up surveys, two had five follow-up surveys and two had six follow-up surveys. The average mean score for follow-up surveys was two. Figure III shows a bar graph of the number of follow-ups for each of the 61 participants. All follow-up surveys for the 61 participants were used in this study to collect an average mean score. By using a variety of follow-up surveys instead of the same number of follow-up surveys, it is possible oral health quality of life and SRQL results were affected. It is difficult to know if participants with only one follow-up experienced the same oral health quality of life and SRQL as a participant who underwent six follow-up appointments. To fully understand if fewer follow-up appointments compared to multiple follow-up appointments for OSA impacts an individual's oral health quality of life and SRQL, further studies are needed.

Conclusion

The results from this study indicated that oral appliances such as mandibular advancement devices do not impact oral health quality of life for individuals with OSA. As expected, patients also experienced self-reported improvement with sleep disturbance, sleep related impairment and sleepiness issues while using an oral appliance. SRQL was improved for patients when using a mandibular advancement device for OSA. There was a weak correlation found between oral health problems and sleep disturbance, sleep related impairment and sleepiness issues.

SECTION 4

TABLES

Table I: Exclusion Criteria for Selection of Participants

The breakdown of exclusion criteria for participants in this study with the number of participants in each exclusion category are provided. All 255 participants are included in this exclusion.

Excluded	# of Participants
Incomplete Surveys	31
No Assessment Survey	78
No Splint Insert Survey	58
No Follow-Up Survey	27

Table II: Mean (SD) Scores by Survey Type

The mean values and standard deviations are provided for each of the survey sections by type of survey. Only complete surveys of all three survey types are included.

Survey Type	Sleep Disturbance	Sleep Related Impairment	Sleepiness	Oral Health Problems
Assessment	9.45 (5.09)	10.58 (6.09)	7.94 (4.22)	1.69 (2.94)
Splint Insert	9.7 (5.2)	10.93 (5.67)	7.18 (4.1)	1.34 (2.32)
Follow-Up	7.42 (4.91)	8.06 (4.82)	5.73 (3.7)	1.63 (2.36)

Table III: Oral Health Problems and Sleep Issues Correlation

Pearson's correlation coefficient was computed between the oral health survey section score and the other sleep issue section scores. Values given are correlation coefficients and 95% confidence intervals.

Survey Type	Sleep Disturbance	Sleep Related Impairment	Sleepiness
Overall	0.29 (0.22, 0.358)	0.305 (0.236, 0.37)	0.08 (0.006, 0.153)
Assessment	0.218 (0.066, 0.36)	0.177 (0.028, 0.318)	0.015 (-0.135, 0.163)
Splint Insert	0.197 (0.045, 0.341)	0.339 (0.198, 0.466)	0.043 (-0.11, 0.194)
Follow-Up	0.386 (0.292, 0.472)	0.383 (0.29, 0.469)	0.112 (0.007, 0.214)

FIGURES

Figure I: Survey Answers by Survey Type

The survey answers for each of the 27 questions are provided. The green bar represents assessment surveys, orange bar represents splint insert surveys and the blue bar represents follow-up surveys.

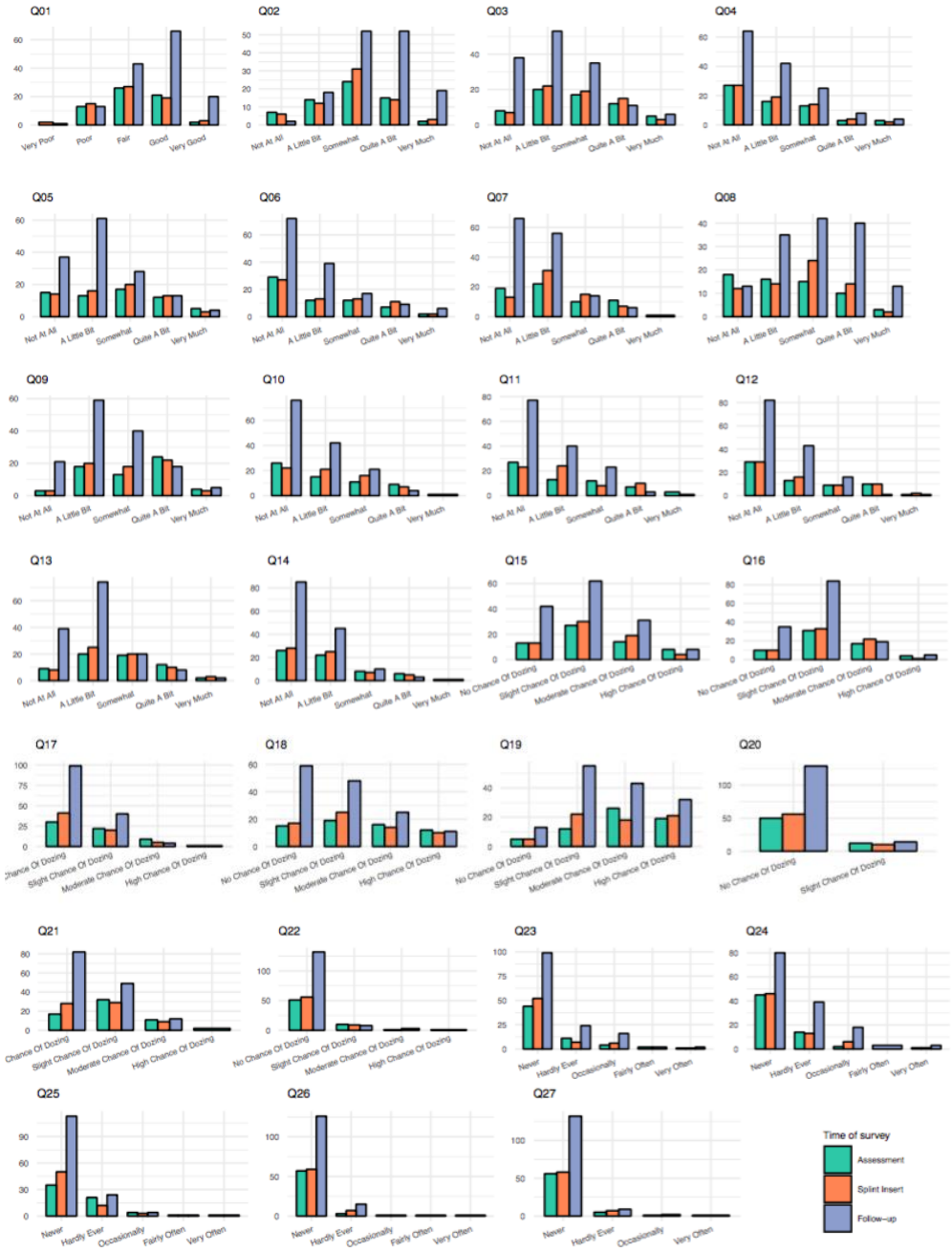


Figure II: Apnea-Hypopnea Index (AHI)

The bar graph represents AHI values for complete surveys of assessment, splint insert and follow-ups only. The x-axis are AHI values and the y-axis are the counts for each range of values. Values less than 5 equal normal (no sleep apnea), 5<15 mild sleep apnea, 15<30 moderate sleep apnea, 30 and greater severe sleep apnea.

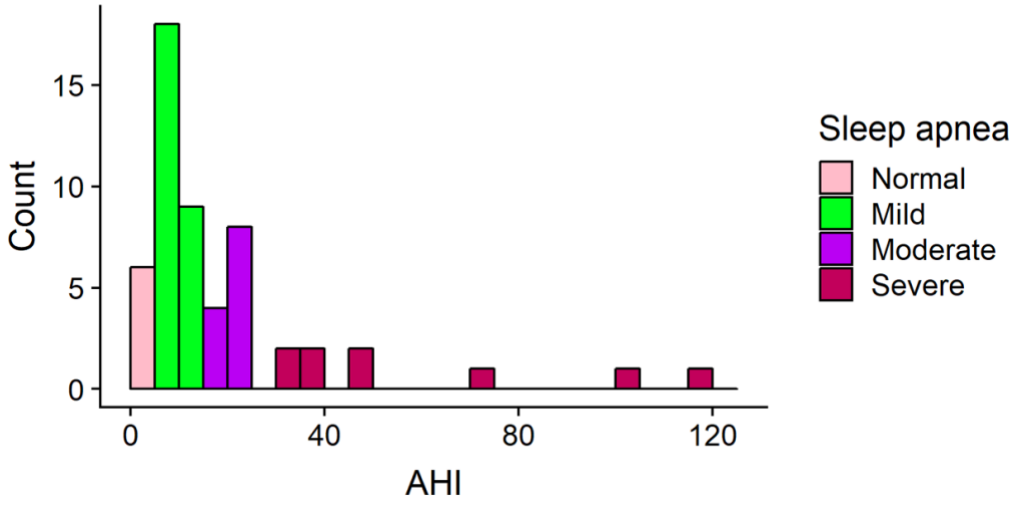
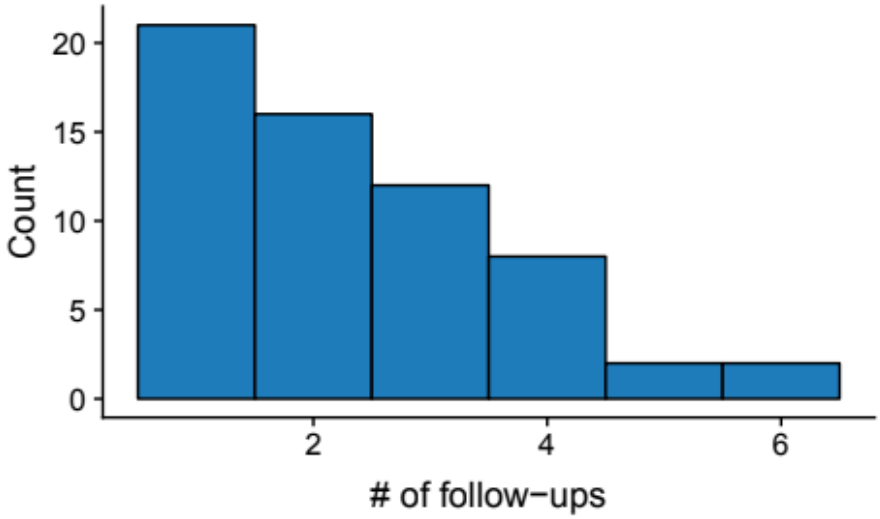


Figure III: Number of Follow-Ups for Participants

The bar graph shows the number of follow-ups for each of the 61 participants. The x-axis are the number of follow-ups and the y-axis are the counts for each participant.



SECTION 5

PRACTICAL APPLICATION

Dental professionals play an essential role in diagnosing and treating patients with OSA. Dental providers perform intra-oral and extra-oral examinations and have access to screening tools to help identity if patients have OSA. Oral characteristics of OSA that dental professionals can identify include enlarged tongue, neck and tonsil size.[4] Through proper screenings and assessments, dental providers play a major role in identifying OSA patients and can help refer patients to their medical physician for further diagnosis and treatment.

The information gained in this study will further enrich the knowledge of dental professionals when screening, identifying, and treating OSA for patients. Dental providers can now inform patients that wearing oral appliances such as a mandibular advancement device do not impact oral health quality of life. Dental professionals can inform patients that sleep disturbance, sleep related impairment and sleepiness issues can improve while using an oral appliance. Patients will be more likely to sleep throughout the night without pauses or shallow breathing that can awaken patients due to their OSA. Patients may feel rested during the day and have an overall improved quality of life. Dental providers can also inform patients that there is a weak correlation between sleep-related quality of life and oral health quality of life while undergoing oral appliance treatment for OSA. Patients do not have to worry about their teeth, mouth or jaw being in pain while wearing oral appliances to treat OSA.

It is important for dental professionals to inform and educate their patients on this new research. Patients can feel more at ease when being diagnosed with OSA with a

better understanding of what their quality of life will be while using oral appliances. Patients can make informed decisions regarding treatment options and the outcomes that follow. OSA affects many individuals. The more knowledge dental professionals can provide to patients for treatment of their OSA, the better quality of life patients can experience.

SECTION 6

COMPREHENSIVE LIST OF REFERENCES

1. Rodgers B. Breaking through limbo: experiences of adults living with obstructive sleep apnea. Behav Sleep Med. 2014 May 4; 12(3): 183–197.
2. Borzan C, Coman A, Todea D, Vesa C. Obstructive sleep apnea syndrome and the quality of life. Clujul med. 2016; 89(3): 390–395.
3. Batool-Anwar S, Goodwin J, Kushida C, Nichols D, Quan S, Simon R, Walsh J. Impact of continuous positive airway pressure (cpap) on quality of life in patients with obstructive sleep apnea (osa). J Sleep Res. 2016 Dec; 25(6): 731–738.
4. Cistulli PA, Gagnadoux F, Kushida CA, Marklund M, Sutherland K, Tsuda H, Vanderveken OM; on behalf of the ORANGE-Registry. Oral appliance treatment for obstructive sleep apnea: an update. J Clin Sleep Med. 2014;10(2):215-227.
5. Nordin E, Stenberg M, Tegelberg A. Obstructive sleep apnoea: patients experiences of oral appliance treatment. J Oral Rehabilitation. 2016;43; 435-442.
6. Billings ME. Putting some teeth into it: connecting periodontitis with sleep apnea. Sleep. 2015;38(8):1153–1154.
7. Braem MJ, Dieltjens M, Van Haesendonck G, Heyning CM, Kastoer C, Shivalkar B, Van De, Vanderveken OM, Vrints C. Cardiovascular benefits of oral appliance therapy in obstructive sleep apnea: a systematic review. J Dental Sleep Med. 2015;2(1):9–14.
8. Nannapaneni S, Ramar K, Surani S. Effect of obstructive sleep apnea on type 2 diabetes mellitus: a comprehensive literature review. World J Diabetes. 2013; 4(6): 238-244.
9. Almeida FR, Foley JH, Kania A, Lowe AA, Mejza F, Nastałek P, Niżankowska-Jędrzejczyk A, Niżankowska- Mogilnicka E, Undas A. Modulation of inflammatory and hemostatic markers in obstructive sleep apnea patients treated with mandibular advancement splints: a parallel, controlled trial. J Clin Sleep Med. 2014;10(3):255-262.
10. Bair E, Dubner R, Diatchenko L, Essick GK, Fillingim R Greenspan JD, Knott C, Maixner W, Miller VE, Ohrbach R, Slade GD, Sanders AE. Sleep apnea symptoms and risk of temporomandibular disorder: OPPERA Cohort. JDR Clinical Research Supplement. 2013 Jul. Vol. 92, supple no. 1.
11. Näpänkangas R, Raunio A, Raustia A, Sipilä K. Effect of mandibular advancement device therapy on the signs and symptoms of temporomandibular disorders. J Oral Maxillofac Res. 2012;3(4):e5.
12. Chahine L. Challenges in managing the side effects of oral appliance therapy. J Dental Sleep Med. 2015;2(2):55–56.
13. Brignardello-Petersen R, Kendzerska TB, Leung RS, Smith PM, Tomlinson GA. Evaluation of the measurement properties of the Epworth sleepiness scale: A systematic review. Sleep Med Rev. 2014 Aug;18(4):321-31.
14. Kaspers G, Terwee C, Van Litsenburg R, Van Kooten J, Yoder W. Validation of the PROMIS sleep disturbance and sleep-related impairment item banks in dutch adolescents. Qual Life Res. 2018 Apr; 1-10.

15. Flynn P, John M, Kohli N, Naik A, Self K. Validation of the english-language version of 5-item oral health impact profile. J Prosthodont Res. 2016 Apr; 60(2): 85–91.
16. Mittal H, John MT, Sekulic S, Theis-Mahon N, Rener-Sitar K. Patient-reported outcome measures for adult dental patients: a systematic review. J Evid Based Dent Pract. 2019. 19(1):53-70.
17. Waller N, John MT, Feuerstahler L, Baba K, Larsson P, Peršić S, Kende D,Reißmann DR, Rener-Sitar K. A 7-day recall period for a clinical application of the oral health impact profile questionnaire. Clin Oral Investig. 2016 Jan; 20(1):91-9.
18. John MT, Miglioretti DL, LeResche L, Koepsell TD, Hujoel P, Micheelis W. German short forms of the oral health impact profile. Community Dent Oral Epidemiol. 34(4):277-288. 2006.
19. Crainiceanu CM, Gottlieb DJ, Ho V, Punjabi NM, Redline S. Calibration model for apnea-hypopnea indices: impact of alternative criteria for hypopneas. Sleep. 2015 Dec; 1;38(12):1887-92.
20. Borsini E, Nigro C, Nogueira F. Apnea-hypopnea index in sleep studies and the risk of over-simplification. Sleep Sci. 2018 Jan-Feb;11(1):45-48.

SECTION 7

APPENDICES

APPENDIX A: IRB APPROVAL

Project ID: 1503M64546

Primary Investigator: Mike John

Title: To Correlate the 8-item Epworth Sleepiness Scale with the PROMIS Sleep Disturbance Scale

Protocol Type: Modification

Approval Date: November 2, 2018

Number of Subjects Approved: 255

Personnel:

Mike John (johnx055@umn.edu), Primary Investigator

Sheila M. Riggs (sriggs@umn.edu), Advisor

APPENDIX B: SURVEY INSTRUMENT

Sleep and Oral Health Survey

Sleep Disturbance

In the past 7 days…

	Very Poor	**Poor**	**Fair**	**Good**	**Very Good**
My sleep quality was					
	Not at all	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
My Sleep was refreshing					
I had a problem with my sleep					
I had difficulty falling asleep					
My sleep was restless					
I tried hard to get to sleep					

Sleep Related Impairment

In the past 7 days…

	Not at all	A little bit	Somewhat	Quite a bit	Very much
I had a hard time getting things done because I was sleepy					
I felt alert when I woke up					
I felt tired					
I had problems during the day because of poor sleep					
I had a hard time concentrating because of poor sleep					
I felt irritable because of poor sleep					
I was sleepy during the daytime					
I had trouble staying awake during the day					

Sleepiness

How likely are you to doze off or fall asleep in the following situations?

You should rate your chances of dozing off, not just feeling tired. Even if you have not done some of these things recently try to determine how they would have affected you.

	No chance of dozing	**Slight chance of dozing**	**Moderate chance of dozing**	**High chance of dozing**
Sitting and reading				
Watching TV				
Sitting inactive in a public place (e.g., a theater or a meeting)				
As a passenger in a car for an hour without a break				
Lying down to rest in the afternoon when circumstances permit				
Sitting and talking to someone				
Sitting quietly after a lunch without alcohol				
In a car, while stopped for a few minutes in traffic				

Oral Health Problems

How often have you had the following problem in the past 7 days?

	Very Often	Fairly Often	Occasionally	Hardly Ever	Never
Have you had difficulty chewing any foods because of problems with your teeth, mouth, dentures or jaws?					
Have you had painful aching in your mouth?					
Have you felt uncomfortable about the appearance of your teeth, mouth, dentures or jaws?					
Have you felt that there has been less flavor in your food because of problems with your teeth, mouth, dentures or jaws?					
Have you had difficulty doing your usual jobs because of problems with your teeth, mouth, dentures or jaws?					